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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,424	07/18/2000	Yoichi Taya	49979	9451

7590

07/03/2002

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 07/03/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/618,424

Applicant(s)

TAYA ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claim 23 is objected to because of the following informalities: claim 23 is dependent on claim 2, which is no longer pending in this application. Appropriate correction is required. For purposes of this office action, claim 23 is being treated as dependent on claim 16.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 16 recites the limitations "the presence" and "the absence." There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 16-19, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lill et al. (Nature, 1997).

Lill et al. teach that p300/CBP (which is considered to be an acetyltransferase) binds to p53 in the absence of viral oncoproteins. The reference also teaches that E1A disrupts binding of p300/CBP to p53 by binding to p300/CBP. The reference teaches the tagging of p53 with green fluorescent protein in a binding assay to show the binding of p300/CBP to p53. However, when E1A is cotransfected with GFP-P53 and epitope tagged p300, binding does not occur. The reference does not teach a screening assay of the use of biotin to label the peptide substrate.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the method of Lill et al. to screen a test compound because screening assays are very well known in the art, and a skilled artisan would have known that the evaluation of a test compound merely required determining the levels of analyte in the presence and absence of the compound. In addition, it would have been obvious to use biotin as a label with the method

of Lill et al. because the biotin/avidin detection system is very well known in the art and is commonly used for detection purposes.

9. Claims 16-19, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al. (Cell, 1997).

Gu et al. teach that p53 is a substrate for p300 acetyltransferase. P53 was labeled by acetyl CoA, but labeling required the presence of both acetyl CoA and p300. The reference also teaches that bacterially produced p53 is inactive in DNA binding, but binding can be activated by anti-p53 monoclonal antibody. Acetylation of p300 also dramatically increases the DNA-binding activity if fixed amounts of p53. The reference does not teach a screening assay of the use of biotin to label the peptide substrate.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the method of Gu et al. to screen a test compound because screening assays are very well known in the art, and a skilled artisan would have known that the evaluation of a test compound merely required determining the levels of analyte in the presence and absence of the compound. In addition, it would have been obvious to use biotin as a label with the method of Gu et al. because the biotin/avidin detection system is very well known in the art and is commonly used for detection purposes.

10. Claims 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lill et al. (Nature, 1997) or Gu et al. (Cell, 1997) in view of Poethke et al. (J. Neuroimmun., 1997).

Lill et al. and Gu et al. teach acetyltransferase assays, as discussed above. However, neither of the references teaches the use of ELISA.

Poethke et al. teach the detection Choline acetyltransferase using ELISA, wherein peptide antibodies absorbed to the surface of polystyrene beads were used as the capture reagent. Monoclonal antibodies were then used to detect the immobilized acetyltransferase.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use an ELISA assay as taught by Poethke et al. with the methods of Lill et al. or Gu et al. because the use of immunoassays, such as ELISA, are extremely well known in the art for the detection of various analytes, and one could have easily used this method of detection with a reasonable expectation of success.

Response to Arguments

11. Applicant's arguments filed April 4, 2002 have been fully considered and are persuasive to overcome the 35 USC 102 rejections over the Lill, Gu, Scolnick and Poethke references. However, applicant's amendments have necessitated the new 35 USC 103 rejections presented herein.

12. Applicant's arguments that the recitations of "the presence" and "the absence" do not lack antecedent basis due to their common usage is unconvincing. While these terms may be commonly used, this fact does not obviate the need for proper antecedent basis. As such, applicant should change these terms to "a presence" and "an absence", respectively.

13. Applicant's argument that the Lill reference does not describe any acetyltransferase activity of p300/CBP is correct. However, it is inherent that this complex has acetyltransferase activity and therefore does not need to be specifically stated. For evidence of this inherent property of this complex, applicant is directed to Gu et al. as an example. Therefore, since the acetyltransferase activity of p300/CBP is an inherent property of the complex, it follows then

that when p/300CBP binds to p53, it inherently acetylates p53. Applicant's argument that the reference fails to disclose or teach the step of comparing the amount of substrate to a control is true. However, since Lill et al. has now been applied under 35 USC 103, the reference is not required to disclose every element of the claims. If this had been the case, it would have been applied under 35 USC 102.

14. Applicant's arguments that the Gu reference does not teach the use of anti-acetylated antibodies are erroneous. Although the reference does teach the use of radiolabeled sodium acetate, as applicant contends, the reference also teaches the use of anti-p53 antibodies.

15. Applicant's arguments with regard to the 103 rejection of the previous office action is moot, as this argument relies solely on the contention that the references were improperly applied under 35 USC 102, the rejections of which have been withdrawn.

Conclusion

Claims 16-23 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509.


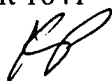
The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

June 29, 2002



LONG V. LE
SUPERVISORY PATENT EXAMINER
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06/29/02